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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,974	03/24/2004	Charles C. Hart	A-3124-AL	6970

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EXAMINER	
MEHTA, BHISMA	
ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,974	HART ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38,48-72 and 74-76* is/are pending in the application.

4a) Of the above claim(s) *10-19,27-33,48-72 and 74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 20-26, 34-38, 75, and 76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-9, 20-24, 34-38, 75, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine (U.S. Patent No. 6,520,939) in view of Steigerwald (U.S. Patent No. 4,895,346). Lafontaine disclose a surgical access device having an elongate tubular member (110), a polymeric septum seal (140) formed at the distal end of the tubular member, and a zero seal (130) disposed at the distal end of the tubular member and distal to the septum seal. The septum seal has an orifice in the form of a hole or piercing which is configured to receive an instrument. The zero seal is coupled to the septum seal and has properties to float with the septum seal relative to the tubular member. Lafontaine discloses the surgical access device substantially as claimed. However, Lafontaine is silent to the specifics of the septum seal comprising an elastomeric sheet having an orifice through the elastomeric sheet. Steigerwald discloses a surgical access device having a septum seal (76) comprising an elastomeric sheet and an orifice through the elastomeric sheet (Figure 1 and lines 12-45 of column 3) and a zero seal (82) distal to the septum seal which is sized and configured to seal when no instrument is present. The orifice is in the form of a hole or piercing which is configured to receive an instrument. Steigewald also discloses another embodiment for

a septum seal as seen in Figure 11 (lines 46-63 of column 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the septum seal of Lafontaine with the septum seal of Steigerwald as both Lafontaine and Steigerwald disclose surgical access devices having two seals to ensure that a fluid tight seal is achieved when an instrument is placed through the seals (lines 46-64 of column 4 of Lafontaine and lines 20-48 of column 4 of Steigerwald) and Steigerwald teaches that this fluid-tight seal can also be achieved with a septum seal comprising an elastomeric sheet and an orifice.

As to claim 2, see lines 5-20 of column 3. As to claims 3 and 4, the zero seal is a duckbill seal with an intersecting sealing portion (134A) or a double duckbill seal with two or more intersecting sealing portions (134B). As to claims 5 and 6, see Figure 3. As to claims 7-9, see lines 6-22 of column 4. The device also has a placement device (14, 40, 50). As to claim 21, the placement device is an obturator. As to claim 22, the placement device includes an elongate shaft with a proximal end, a mid-portion, and a distal end. As to claim 23, the proximal end of the elongate shaft has a handle and the mid-portion of the elongate shaft has a reduced profile (see Figure 1). As to claim 34, the seal has opposing lip portions (132) separated by a slit portion. As to claims 35 and 36, see lines 31-46 of column 4. As to claims 37 and 38, the lip portions are capable of allowing a surgical item such as a surgical suture to extend through the slit portion without disrupting a seal formed by the closure of the opposing lip portions.

3. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Steigerwald as applied to claim 22 above, and further in view

of Green et al (U.S. Patent 6,497,716). Lafontaine in view of Steigerwald disclose the device substantially as claimed. However, Lafontaine is silent on the specifics of the distal end of the placement device being shaped like an hourglass or comprising a tapered, cone-shaped member. Green et al disclose a placement device (22) which is used to place an access device (14) where the distal end of the placement device is shaped like an hourglass and has a tapered, cone-shaped member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the placement device of Lafontaine with the placement device of Green et al as both Lafontaine and Green et al disclose surgical access devices and placement devices for placing the access devices and Green et al disclose that it is well known to use a placement device having a distal end shaped like an hourglass and a tapered, cone-shaped member to place the access device.

Response to Arguments

4. Applicant's arguments in lines 1-10 of page 15 filed August 17, 2009 have been fully considered but they are not persuasive. The status of claim 74 is maintained as being withdrawn. This claim is drawn to a non-elected species as the elastomeric sheet comprising a generally conical profile is not shown in the elected species. These is a lack of disclosure of the "generally conical profile" in the specification as “generally conical profile" is considered to be encompass a shape where the base is a circle and the sides taper up to a point. This is also not seen in the elected species (Figures 6-10) as the sides of the elastomeric sheet of the septum seal do not taper to a point.

5. Applicant's arguments with respect to claims 1-9, 20-26, 34-38, 75, and 76 have been considered but are moot in view of the new ground(s) of rejection. As to Applicant's arguments in lines 1-10 of page 19, the septum seal (140) of Lafontaine is considered to be integrally formed at the distal end of the tubular member (110) as Lafontaine discloses that it is an integral part of the tubular member (lines 16-22 of column 4). Therefore, the substitution of the septum seal of Lafontaine with the septum seal of Steigerwald would result in the septum seal of Steigerwald being integrally formed at the distal end of the tubular member of Lafontaine. Furthermore, Lafontaine discloses that the septum seal (140) can be positioned at any portion of the tubular member (110) or the hub (120) (lines 6-16 of column 4). Therefore, even though Steigerwald discloses that the septum seal (76) is at a proximal position of the tubular member, the septum seal (76) can be formed at the distal end of the tubular member (110) of Lafontaine as Lafontaine teaches that the septum seal can be incorporated at different positions. As to Applicant's arguments in lines 16-20 of page 19, the septum seal or valve member (76) of Steigerwald is not a disk-shaped gasket and thus is not similar to the ones in Figures 2A and 2B of Lafontaine. Therefore, one skilled in the art would not be dissuaded by Lafontaine to modify the device to include the septum seal of Steigerwald. As to Applicant's arguments in lines 3-17 of page 20, Applicant's remarks regarding the indication in Steigerwald that a compression member must be adjusted in order for the septum seals or valve members to seal effectively in all conditions is unclear as this disclosure is not found in Steigerwald. In lines 20-48 of column 4, Steigerwald discloses that the septum seal or valve members (76 and 82) seal against

the catheter and that the compression member may be adjusted. However, there is no disclosure in Steigerwald that the compression member is required as Steigerwald discloses that the valve members seal against the catheter such that air cannot enter the tubular member and blood cannot pass out through the valve members without any adjustment of the compression member. Therefore, substituting the septum seal of Lafontaine with the septum seal of Steigerwald as discussed above would not require a compression member in order for the device to be operative.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767